

The Vioxx Story

In his book [*Doubt is Their Product*](#), David Michaels (currently head of OSHA) tells the Vioxx story in a way I'd never heard before (pp. 146-147):

Aspirin and Aleve work by inhibiting the COX-1 and COX-2 enzymes. Inhibiting COX-2 lessens pain, but inhibiting COX-1 causes stomach problems like bleeding and ulcers. So the new class of COX-2 inhibitors, like Vioxx, were supposed to stop the pain without the nasty stomach side-effects.

Of course, aspirin has the additional side effect of protecting your heart, so when they designed a study demonstrating the benefits of Vioxx, they made sure to a) exclude anyone with heart problems, and b) compare it against Aleve, which doesn't have the same beneficial effects for the heart.

The result of the study was shocking: despite all these efforts, the people who took Vioxx had 4 times the number of heart problems as the people who took Aleve. So what did the makers of Vioxx do? They told the FDA that this study showed how incredibly effective *Aleve* was at reducing heart attacks! Yes, it wasn't that Vioxx increased the risk of a heart attack by 4 times — it was that Aleve magically reduced heart attacks by 80%.

And the FDA believed them.

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February 10, 2010